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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	David Stern et al.
Serial No.	:	08/997,464 Examiner: J. Kerr
Filing Date	:	December 23, 1997 Art Unit: 1633
For	:	A METHOD FOR EVALUATING THE ABILITY OF A COMPOUND TO INHIBIT NEUROTOXICITY

1185 Avenue of the Americas
New York, New York 10036
April 1, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

COMMUNICATION IN RESPONSE TO MARCH 2, 1999 OFFICE ACTION

This Communication is submitted in response to the March 2, 1999 Office Action which was issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the March 2, 1999 Office Action is due on April 1, 1999. Thus, this Communication is being timely filed.

Election/Restriction

The Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

Group I. Claims 1-5, 11, and 12, drawn to a method for evaluating the ability of a compound to inhibit neurotoxicity, and a pharmaceutical composition containing a compound identified by the method, classified in class 435, subclasses 4,7.1,7.2, and 7.21, and class 424, subclasses 9.1, for example;

Group II. Claims 6-10, drawn to a method for evaluating the ability

of a compound to inhibit binding of an amyloid-B peptide to a receptor, classified in class 435, subclasses 4, 7.1, 7.2, and 7.21;

Group III. Claims 11-20, drawn to a method of treating a neurodegeneration condition with a pharmaceutical composition, classified in class 424, subclasses 9.1 and 9.2, for example;

Group IV. Claims 21-30, drawn to a transgenic animal which expresses human presenilin-2 protein or a mutant human presenilin-2 protein and a human receptor for advanced glycation end product protein, and a diagnostic method using the transgenic animal, classified in class 800, subclasses, 3, 8, 9, and 13, for example; and

Group V. Claims 31-33, drawn to cells containing a recombinant nucleic acid comprising DNA encoding mutant prenilin-2 protein and encoding a receptor for advanced glycation end product protein, classified in class 435, subclasses 172.1, 172.3, 368, and 455, for example.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner asserted that inventions I, II, V and III-IV are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.4, MPEP §808.01). The Examiner stated that in the instant case the inventions of groups I and II are drawn to in vitro diagnostic methods which do not

require the inventions of group III, drawn to a treatment method, or the invention of group IV, drawn to non-human transgenic animal and methods of use, as the diagnostic methods of Inventions I and II can be performed in vitro with transformed cells, while the method on Invention IV requires a non-human transgenic animal for reduction to practice.

The Examiner stated that Inventions I and II are distinct from Invention V in that the diagnostic methods of Inventions I and II do not require the cells of group V, i.e., cells containing naturally occurring mutations in the human presenilin-2 protein can be utilized in the diagnostic methods. The Examiner stated that moreover, the cells of group V can be used for purposes other that in the diagnostic methods of Inventions I and II, e.g., the cells can be used as a source of mutated human presenilin-2 protein for the purpose of generating antibodies.

The Examiner stated that Inventions I and II, drawn to diagnostic methods, are patentably distinct as the methods require different technical considerations, different reagents, and different mechanisms of action. The Examiner stated that for example, the method of Invention I requires a determination of cell death, a mechanism of action not required to reduce to practice the method of Invention II, which requires measurements of binding activities.

The Examiner asserted that Invention III, drawn to a method for treating neurodegenarion is distinct form the inventions of groups IV and V as the method does not require the use of a transgenic animal or host cells containing recombinant nucleic acids.

The Examiner noted that Invention IV, drawn to transgenic animals and method of use, is distinct form Invention V, drawn to cells containing recombinant nucleic acid in that the transgenic animals

are used for in vivo diagnostics while the cells can be used for in vitro diagnostics.

The Examiner stated that the several inventions above have acquired a separate status in the art as a separate subject of inventive effect and require independent searches. The examiner stated that the search for each of the above inventions is not co-extensive particularly with regard to the literature search. The examiner further stated that, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

The Examiner further stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner noted that a telephone call was made John P. White on 2/18/99 to request an oral election to the above restriction requirement, but did not result in an election being made.

The Examiner reminded applicant that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R §1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 §C.F.R 1.48 (b) and by the fee required under 37 C.F.R §1.17(h).

The Examiner stated that in order for the response to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed

(37 CFR §1.143).

In response, applicants hereby provisionally elect with traverse to prosecute the invention of Group I, i.e. claims 1-5, 11 and 12.

However, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine Groups I-V together in view of the following remarks. 35 U.S.C. § 121 states "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions" (emphasis added). Contrary to the requirement of 35 U.S.C. § 121, the Examiner has found that the inventions are distinct without also finding them to be independent inventions. In fact, the claims of Groups I-V are dependent (related) inventions. In defining the term "related," the M.P.E.P. states, "the term 'related' is used as an alternative for 'dependent' in referring to subjects other than independent subjects." M.P.E.P. § 802.01. Groups I-V are dependent since all involve compounds which inhibit neurotoxicity. Therefore, applicants respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. § 802.01.

Further, applicants respectfully point out that under M.P.E.P. § 803, the Examiner must examine the application on the merits, even if it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely: (1) the invention must be independent and distinct; and (2) there must be a serious burden on the Examiner if restriction is not required. Applicants contend that there would not be a serious burden on the Examiner if restriction is not required. This is so

because a search of the prior art for subject matter defined by claims in any one of Groups I-V would necessarily overlap and possibly identify art pertaining to the subject matter defined by claims in any of the other Groups. For example, a search of the prior art for a method for evaluating the ability of a compound to inhibit neurotoxicity (Group I, claims 1-5, 11 and 12) would necessarily overlap and possibly identify art pertaining to a method for evaluating the ability of a compound to inhibit binding of amyloid beta peptide to a receptor (Group II, claims 6-10) and to cells containing a recombinant nucleic acid comprising DNA encoding mutant presenilin-2 protein and encoding a receptor for advanced glycation end product protein (Group V, claims 31-33). The Examiner indicated that class 435 would be searched for each of these groups. Therefore, it would not be a serious burden for the Examiner to examine Groups I-II and V together.

Accordingly, in view of the foregoing remarks, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine the claims in Groups I-II and V together.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents
Washington, D.C. 20231.

4/1/99
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